CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 074611

Trade Name : NICOTINE TRANSDERMAL SYSTEM USP 14 MG/DAY

Generic Name: Nicotine Transdermal System USP 14 mg/day
Sponsor : Sano Corporation

Approval Date: October 20, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 074611

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tenative Approval Letter				
Approvable Letter				
Final Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)	X			
Administrative Document(s)				
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 074611

APPROVAL LETTER

ANDAs 74-611 (14 mg/day)
74-612 (21 mg/day)
74-645 (7 mg/day)

OCT 20 1997

Sano Corporation
Attention: Diane Servello
3250 Commerce Parkway
Miramar, FL 33025

Dear Madam:

This is in reference to your abbreviated new drug applications dated January 20, 1995 (74-611 and 74-612), and March 9, 1995 (74-645), submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nicotine Transdermal System, USP.

Reference is also made to your amendments submitted to each application dated July 31, 1996; April 25, May 9, July 15, August 29, September 2, and October 16, 1997. We also acknowledge your amendments dated April 21, April 25, and May 19, 1995; August 19, 1996; and June 4, June 18, June 19, July 2, and July 3, 1997 submitted to ANDA 74-612.

The listed drug product referenced in your applications is subject to periods of patent protection which expire on May 21, 2008, (patent 5,016,652) and January 23, 2005 (patent 4,597,961). Your applications contain Paragraph IV certifications to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(4)(B)(iii) of the Act provides that "approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received." You have notified FDA that Sano has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Sano within the statutory forty-five day period.

We have completed the review of these abbreviated applications and have concluded that the drugs are safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Nicotine Transdermal System, 7 mg/day, 14 mg/day, and 21 mg/day to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Habitrol 7 mg/day, 14 mg/day, and 21 mg/day, respectively, of Novartis Consumer Health, Inc.). Your drug release testing should be incorporated into the

stability and quality control programs using the same methods proposed in your applications.

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require an approved supplemental application before the changes may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of these drugs.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

10/20/97

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

FINAL PRINTED LABELING

Inactive Components:
Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
Sano Corporation
Miramar, FL 33025

3 3215-1235-30 8

Nicotine Transdermal System

Contents: 30 Transdermal Systems

FOR TRANSDERMAL USE ONLY
DO NOT USE IF SEAL ON POUCH IS BROKEN
WARNING: KEEP OUT OF REACH OF CHILDREN.

14
mg/day

One 19.3 cm² system which contains 31.5 mg of nicotine.

Caution: Federal law prohibits dispensing without prescription.

12

Dosage & Administration:
Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH.

Storage:
Do not store above 30°C (86°F).

See patient instructions for disposal information.

Contains NICOTINE, the addictive agent in cigarettes.

See bottom panel for lot number and expiration date.

Nicotine Transdermal System

Contents: 30 Transdermal Systems

FOR TRANSDERMAL USE ONLY
DO NOT USE IF SEAL ON POUCH IS BROKEN
WARNING: KEEP OUT OF REACH OF CHILDREN.

14 mg/day

One 19.3 cm² system which contains 31.5 mg of nicotine.

Caution: Federal law prohibits dispensing without prescription.

14 mg/day

Contents: 14 Transdermal Systems
For Transdermal Use Only

Nicotine Transdermal System

Contents: 14 Transdermal Systems

FOR TRANSDERMAL USE ONLY
DO NOT USE IF SEAL ON POUCH IS BROKEN
WARNING: KEEP OUT OF REACH OF CHILDREN.

14 mg/day

One 19.3 cm² system which contains 31.5 mg of nicotine.

Caution: Federal law prohibits dispensing without prescription.

Inactive Components:
Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
Sano Corporation
Miramar, FL 33025

3 3215-1235-14 8

Dosage & Administration:
Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH.

Storage:
Do not store above 30°C (86°F).

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Contains NICOTINE, the addictive agent in cigarettes.

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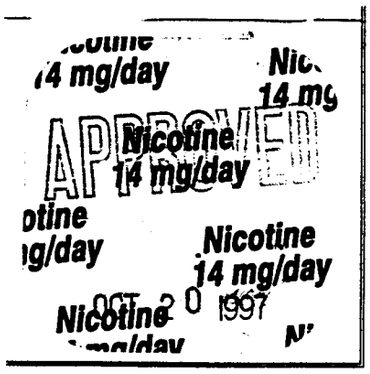
14 mg/day
Nic
14 mg
APPROVED
Nicotine
14 mg/day
otine
g/day
Nicotine
14 mg/day
OCT 20 1997
Nicotine

NICOTINE TRANSDERMAL SYSTEM 14 mg/day

PRIMARY CONTAINER

FRONT

Nicotine Transdermal System

14 mg/day

FOR TRANSDERMAL USE ONLY

DO NOT USE IF SEAL ON POUCH IS BROKEN

WARNING: KEEP OUT OF REACH OF CHILDREN

ZL003 09/95

One 19.3cm² system which contains 31.5 mg of nicotine.

***Caution:** Federal law prohibits dispensing without prescription.*

OCT 1 0 1997

[redacted]

BACK

Contents: 1 System

Dosage & Administration: Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH

Storage: Do not store above 30°C (86°F).

See patient instructions for disposal information.

Contains NICOTINE, the addictive agent in cigarettes.

Inactive Components: Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
SANO CORPORATION
Miramar, FL 33025

[illegible] 1997

ZL013 09/95

FRONT

Nicotine Transdermal System

14 mg/day

FOR TRANSDERMAL USE ONLY

DO NOT USE IF SEAL ON POUCH IS BROKEN

WARNING: KEEP OUT OF REACH OF CHILDREN.

ZL003 09/95

One 19.3cm² system which contains 31.5 mg of nicotine.

***Caution:** Federal law prohibits dispensing without prescription.*

[illegible] 1997

[redacted]

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Dosage & Administration: Follow dosing instructions as directed by your physician. For application, see patient instructions.

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Contains NICOTINE, the addictive agent in cigarettes.

Inactive Components: Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
SANO CORPORATION
Miramar, FL 33025

OCT 20 19[illegible]

ZL013 09/95

OCT 20 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS

DIVISION OF CHEMISTRY II

ANDA REVIEW

1. CHEMIST'S REVIEW NO. 4

2. ANDA # 74-611

3. NAME AND ADDRESS OF APPLICANT

Sano Corporation
Attention: Diane Servello
3250 Commerce Parkway
Miramar, FL 33025

4. LEGAL BASIS for ANDA SUBMISSION

page 100007
Listed Drug: Habitrol™ Nicotine Transdermal System/Ciba Corporation
Patent#s 5016652 and 4597961 expire 5.21.2008 and 7.1.2003, respectively. Exclusivity expired 11.7.94.

5. SUPPLEMENT(s) None

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Nicotine Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR: None

9. AMENDMENTS AND OTHER DATES:

Applicant:

01.20.95: Original
04.13.95: Amendment (Debarment Certification)
04.24.95: Amendment (Notice of certification of noninfringement of patent#s 5016652 and 4597961
06.7.95: Correspondence
10.20.95: Amendment
11.01.95: Amendment
02.12.96: Amendment
06.04.96: Amendment
07.31.96: Amendment
08.14.96: Amendment
10.10.96: Amendment
02.12.97: Amendment **Subject of this review**

FDA:

04.06.95: Acknowledge receipt
08.16.95: NA letter #1
05.29.96: NA letter #2
01.14.97: NA letter #3

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC

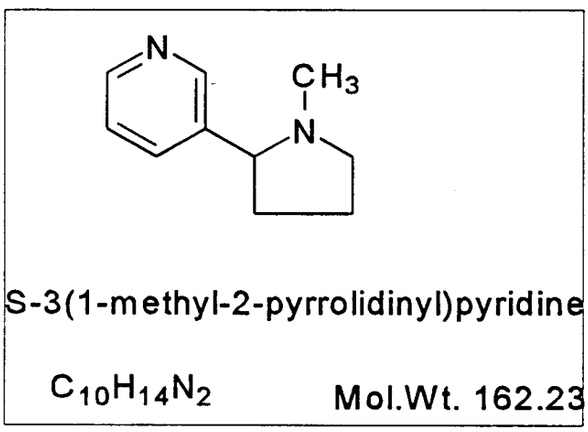
Relief of Nicotine Withdrawal R_x

12. RELATED IND/NDA/DMF(s) See review element #37

13. DOSAGE FORM 14. POTENCY

Transdermal Patch 14 mg/day

15. CHEMICAL NAME AND STRUCTURE



Nicotine

16. RECORDS AND REPORTS None

17. COMMENTS

a. The following DMFs are satisfactory.
b. The Chemistry, Manufacturing, and Controls are satisfactory.
c. Non compendial drug substance and drug product. MV satisfactory, Southeast Regional Labs, 9.19.96.

d. EER submitted 4.3.96; satisfactory, 7.22.96.
e. Professional labeling - A. Payne, not satisfactory, 7.31.95; J. White - pending
f. Bio-review pending. Bio-review not satisfactory, per e-mail, M. Anderson, 11.25.96

18. CONCLUSIONS AND RECOMMENDATIONS

The application is satisfactory in chemistry, manufacturing and controls and may be approved with satisfactory labeling and bio-review.

19. REVIEWER: DATE COMPLETED:

U. V. Venkataram, Ph.D. 03.12.97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

BIOEQUIVALENCE REVIEW(S)

MAR 26 1997

Nicotine Transdermal System
14 mg/day
ANDA #74-611
Reviewer: F. Nouravarsani
74611DW.095

Sano Corporation
Miramar, FL
Submission Date:
October 20, 1995

REVIEW OF A DISSOLUTION TESTING AND A WAIVER REQUEST

Sano has requested a waiver of bioequivalence study requirements for its Test product, Nicotine Transdermal System, 14 mg/day.

The firm's bioequivalence study conducted on its higher strengh test product, Nicotine Transdermal System, 21 mg/day has been found incomplete. Therefore the firm should be informed that, this submission will not be reviewed at this time. The firm should resubmit a waiver request for its test product.

Farahnaz Nouravarsani, Ph.D.
Division of Bioequivalence
Review Branch III

RD INITIALED RMHATRE
FT INITIALED RMHATRE

for RM 3/12/97

Concur:_____ Date: 3/26/97
for Nicholas Fleischer, Ph.D.
Director
Division of Bioequivalence

Fnouravarsani/03-07-97/74611DW.095

CC: ANDA #74-611 (original, duplicate), Nouravarsani, HFD-658, Drug File, Division File

074611

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 074611

Trade Name : NICOTINE TRANSDERMAL SYSTEM USP 14 MG/DAY

Generic Name: Nicotine Transdermal System USP 14 mg/day
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Approval Date: October 20, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 074611

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CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 074611

APPROVAL LETTER

ANDAs 74-611 (14 mg/day)
74-612 (21 mg/day)
74-645 (7 mg/day)

OCT 20 1997

Sano Corporation
Attention: Diane Servello
3250 Commerce Parkway
Miramar, FL 33025

Dear Madam:

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The listed drug product referenced in your applications is subject to periods of patent protection which expire on May 21, 2008, (patent 5,016,652) and January 23, 2005 (patent 4,597,961). Your applications contain Paragraph IV certifications to each patent under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(4)(B)(iii) of the Act provides that "approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received." You have notified FDA that Sano has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Sano within the statutory forty-five day period.

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Sincerely yours,

10/20/97

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

FINAL PRINTED LABELING

Contains: 30 Transdermal Systems
For Transdermal Use Only

Inactive Components:
Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
Sano Corporation
Miramar, FL 33025

3 3215-1235-30 8

Nicotine Transdermal System

Contents:
30 Transdermal Systems

FOR TRANSDERMAL USE ONLY
DO NOT USE IF SEAL ON POUCH IS BROKEN
WARNING: KEEP OUT OF REACH OF CHILDREN.

14
mg/day

One 19.3 cm² system which contains 31.5 mg of nicotine.

Caution: Federal law prohibits dispensing without prescription.

Dosage & Administration:
Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH.

Storage:
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See patient instructions for disposal information.

Contains NICOTINE, the addictive agent in cigarettes.

See bottom panel for lot number and expiration date.

Nicotine Transdermal System

Contents:
30 Transdermal Systems

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14 mg/day

Contents: 14 Transdermal Systems
For Transdermal Use Only

Nicotine Transdermal System

Contents: 14 Transdermal Systems

14 mg/day

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WARNING: KEEP OUT OF REACH OF CHILDREN.

Inactive Components:
Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
Sano Corporation
Miramar, FL 33025

3 3215-1235-14 8

Dosage & Administration:
Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH.

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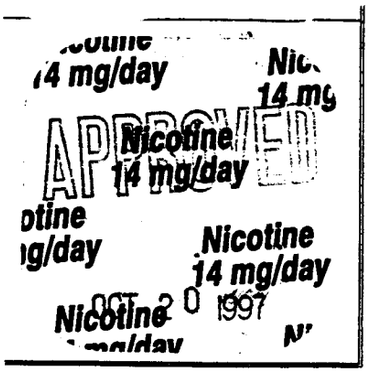
14 mg/day
Nicotine
14 mg/day
APPROVED
Nicotine
14 mg/day
Nicotine
14 mg/day
OCT 20 1997

mango

NICOTINE TRANSDERMAL SYSTEM 14 mg/day

PRIMARY CONTAINER

FRONT

Nicotine Transdermal System

14 mg/day

FOR TRANSDERMAL USE ONLY

DO NOT USE IF SEAL ON POUCH IS BROKEN

WARNING: KEEP OUT OF REACH OF CHILDREN

ZL003 09/95

One 19.3cm² system which contains 31.5 mg of nicotine.

***Caution:** Federal law prohibits dispensing without prescription.*

OCT 20 1997

[redacted]

BACK

Contents: 1 System

Dosage & Administration: Follow dosing instructions as directed by your physician. For application, see patient instructions.

APPLY IMMEDIATELY UPON REMOVAL FROM POUCH

Storage: Do not store above 30°C (86°F).

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Inactive Components: Silicone adhesive, acrylate adhesive, and aluminized polyester.

Manufactured by:
SANO CORPORATION
Miramar, FL 33025

[redacted] 1997

ZL013 09/95

FRONT

Nicotine Transdermal System

14 mg/day

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WARNING: KEEP OUT OF REACH OF CHILDREN.

ZL003 09/95

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[redacted] 1997

[redacted]

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OCT 20 19[redacted]

Manufactured by:
SANO CORPORATION
Miramar, FL 33025

ZL013 09/95

OCT 20 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS

DIVISION OF CHEMISTRY II

ANDA REVIEW

1. CHEMIST'S REVIEW NO. 4

2. ANDA # 74-611

3. NAME AND ADDRESS OF APPLICANT

Sano Corporation
Attention: Diane Servello
3250 Commerce Parkway
Miramar, FL 33025

4. LEGAL BASIS for ANDA SUBMISSION

page 100007
Listed Drug: Habitrol™ Nicotine Transdermal System/Ciba Corporation
Patent#s 5016652 and 4597961 expire 5.21.2008 and 7.1.2003, respectively. Exclusivity expired 11.7.94.

5. SUPPLEMENT(s) None

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Nicotine Transdermal System

8. SUPPLEMENT(s) PROVIDE(s) FOR: None

9. AMENDMENTS AND OTHER DATES:

Applicant:

01.20.95: Original
04.13.95: Amendment (Debarment Certification)
04.24.95: Amendment (Notice of certification of noninfringement of patent#s 5016652 and 4597961
06.7.95: Correspondence
10.20.95: Amendment
11.01.95: Amendment
02.12.96: Amendment
06.04.96: Amendment
07.31.96: Amendment
08.14.96: Amendment
10.10.96: Amendment
02.12.97: Amendment **Subject of this review**

FDA:

04.06.95: Acknowledge receipt
08.16.95: NA letter #1
05.29.96: NA letter #2
01.14.97: NA letter #3

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC

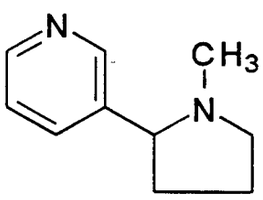
Relief of Nicotine Withdrawal R_x

12. RELATED IND/NDA/DMF(s) See review element #37

13. DOSAGE FORM 14. POTENCY

Transdermal Patch 14 mg/day

15. CHEMICAL NAME AND STRUCTURE



S-3(1-methyl-2-pyrrolidinyl)pyridine

$C_{10}H_{14}N_2$ Mol.Wt. 162.23

Nicotine

16. RECORDS AND REPORTS None

17. COMMENTS

a. The following DMFs are satisfactory·
b. The Chemistry, Manufacturing, and Controls are satisfactory.
c. Non compendial drug substance and drug product. MV satisfactory, Southeast Regional Labs, 9.19.96.

d. EER submitted 4.3.96; satisfactory, 7.22.96.
e. Professional labeling - A. Payne, not satisfactory, 7.31.95; J. White - pending
f. Bio-review pending. Bio-review not satisfactory, per e-mail, M. Anderson, 11.25.96

18. CONCLUSIONS AND RECOMMENDATIONS

The application is satisfactory in chemistry, manufacturing and controls and may be approved with satisfactory labeling and bio-review.

19. REVIEWER: DATE COMPLETED:

U. V. Venkataram, Ph.D. 03.12.97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 074611

BIOEQUIVALENCE REVIEW(S)

MAR 26 1997

Nicotine Transdermal System
14 mg/day
ANDA #74-611
Reviewer: F. Nouravarsani
74611DW.095

Sano Corporation
Miramar, FL
Submission Date:
October 20, 1995

REVIEW OF A DISSOLUTION TESTING AND A WAIVER REQUEST

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Farahnaz Nouravarsani, Ph.D.
Division of Bioequivalence
Review Branch III

RD INITIALED RMHATRE
FT INITIALED RMHATRE

for RM 3/12/97

Concur:_____ Date: 3/26/97
Nicholas Fleischer, Ph.D.
Director
Division of Bioequivalence

Fnouravarsani/03-07-97/74611DW.095

CC: ANDA #74-611 (original, duplicate), Nouravarsani, HFD-658, Drug File, Division File